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PATENT APPLICATION

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robert L. Jaffe, Ph.D.

Serial No.: 09/086,138

Group Art Unit: 1623

Filed: May 28, 1998

Examiner: Ralph Gitomer

For: Determination of Cytotoxic Substances in Whole Effluent Samples

DECLARATION UNDER RULE 132

I, Robert L. Jaffe, declare as follows:

1. I am the inventor of the above-captioned application. As such, I am fully familiar with the invention described and claimed in that application. I make this declaration in response to the Official Action mailed September 27, 1999.
2. In the Official Action, the Examiner stated that "It is noted the present specification on page 2 last paragraph discusses '508 where '508 does not disclose a WET test in which all of the potentially toxic substances from the sample are evaluated in a natural combination. See in '508 Example 5 in column 6 where a WET sample is tested."
3. The whole effluent toxicity (WET) test, as defined by the United States Environmental Protection Agency (EPA), is the aggregate toxic effect of an effluent or receiving (ambient) water measured directly with a toxicity test. The regulation concerns the use of

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whole effluent toxicity (WET) test methods to protect aquatic life in National Pollutant Discharge Elimination (NPDES) data gathering and compliance monitoring under the Clean Water Act.

4. The whole effluent toxicity (WET) test, as defined in the specification, tests for toxicity of the combination of chemical compounds, both organic and inorganic which may be present in an effluent sample, and for the determination of component-toxicity associated with dissolved and particulate materials.
5. The current application concerns whole effluent sampling, or a type of water testing as addressed by the Environmental Protection Agency and whole effluent toxicity, as defined in the specification and number four above. In the current application, suitable starting samples include water, sewage, industrial effluent, and ocean or estuary samples.
6. '508 discusses various types of testing for the flagellate *Tetramitus rostratus*' use in solid, liquid, or gaseous samples.
7. '508 Example 5 in column 6, the poison 2-aminofluorene was added to a liquid sample to test if the flagellates exhibited severe growth and adaption to the specific poison. The flagellates exhibited adaption and continued to a normal growth rate in the presence of 2-

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aminofluorene. The purpose of this test was to show that the flagellate *Tetramitus rostratus* would adapt and continue to grow in the presence of the poison. It suggested that strains of *Tetramitus rostratus* flagellates could be developed which are adapted to specific compounds, groups of compounds or mixtures. Therefore, this was not a whole effluent toxicity test, and all the potentially toxic substances from the sample were not evaluated in natural combination.

8. '508 Example 5 in column 6, and continued the testing of number 6 above in a practical environment. A test outlined in '508 Example 5 in column 6 discusses a test of fumes (or gasses) from a rubber stamp manufacturer, where the flagellates' ability to adapt and become immune to the toxicity was again tested. This observation suggested that strains of *Tetramitus rostratus* flagellates could be developed which are adapted to specific compounds, groups of compounds, or mixtures. This example is not a whole effluent toxicity test because it was contrived to evaluate the flagellates' adaptation and immunity abilities.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States



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Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

dated: January 21, 2000

Robert L. Jaffe
Robert L. Jaffe